

Amendments to the Claims:

This listing of claims will replace all prior versions of the claims in this application:

Listing of Claims:

Claim 1 (original): A method for determining the volume of fluid in the peritoneal cavity of a subject comprising:

- (a) placing measuring electrodes M_{LL} and M_{RL} on the loins of the subject, M_{LL} being placed on the left loin and M_{RL} being placed on the right loin, M_{LL} and M_{RL} defining a loin plane;
- (b) placing measuring electrodes M_{LB} and M_{RB} on the buttocks of the subject, M_{LB} being placed on the left buttock and M_{RB} being placed on the right buttock, M_{LB} and M_{RB} defining a buttock plane;
- (c) placing upper current-providing electrodes I_{LU} and I_{RU} on the subject, I_{LU} being outboard of measuring electrode M_{LL} and I_{RU} being outboard of measuring electrode M_{RL} ;
- (d) placing lower current-providing electrodes I_{RL} and I_{LL} on the subject, I_{RL} being outboard of measuring electrode M_{RB} and I_{LL} being outboard of measuring electrode M_{LB} ;
- (e) connecting upper current-providing electrode I_{LU} to upper current-providing electrode I_{RU} ;
- (f) connecting lower current-providing electrode I_{LL} to lower current-providing electrode I_{RL} ;
- (g) applying current I between the connected upper current-providing electrodes and the connected lower current-providing electrodes;
- (h) measuring the voltage Φ_L between M_{LL} and M_{LB} while current I is applied;

- (i) measuring the voltage Φ_R between M_{RL} and M_{RB} while current I is applied; and
- (j) determining the volume V of fluid in the peritoneal cavity based on the equation:

$$V = (K_P/\sigma) \bullet (L_P^2/R)$$

where:

- (1) K_P is a subject-specific calibration constant;
- (2) σ is the conductivity of the fluid in the peritoneal cavity;
- (3) L_P is the distance between the loin plane and the buttock plane; and
- (4) R is the average of R_L and R_R , where

$$R_L = \Phi_L/I, \text{ and}$$

$$R_R = \Phi_R/I.$$

Claim 2 (original): The method of Claim 1 wherein K_P is determined by:

- (i) performing steps (g), (h), and (i) before the introduction of a predetermined volume V_C of dialysis fluid into the subject's peritoneal cavity to obtain Φ_{LB} and Φ_{RB} , said dialysis fluid having a conductivity σ_C ;
- (ii) performing steps (g), (h), and (i) after the introduction of a predetermined volume V_C of dialysis fluid into the subject's peritoneal cavity to obtain Φ_{LA} and Φ_{RA} ; and
- (iii) determining K_P from the equation:

$$K_P = (\sigma_C) \bullet (V_C/L_P^2) \bullet (R_B R_A)/(R_B - R_A)$$

where

$$R_B = (\Phi_{LB} + \Phi_{RB})/(2I), \text{ and}$$

$$R_A = (\Phi_{LA} + \Phi_{RA})/(2I).$$

Claim 3 (original): The method of Claim 2 where V_C is at least one liter.

Claim 4 (original): The method of Claim 1 wherein K_P is determined by:

- (i) introducing dialysis fluid into the subject's peritoneal cavity;
- (ii) performing steps (g), (h), and (i) to obtain Φ_{LB} and Φ_{RB} ;
- (iii) removing fluid from the subject's peritoneal cavity;
- (iv) performing steps (g), (h), and (i) to obtain Φ_{LA} and Φ_{RA} ; and
- (v) determining K_P from the equation:

$$K_P = (\sigma_C) \bullet (V_C/L_P)^2 \bullet (R_B R_A)/(R_A - R_B)$$

where

$$R_B = (\Phi_{LB} + \Phi_{RB})/(2I),$$

$$R_A = (\Phi_{LA} + \Phi_{RA})/(2I), \text{ and}$$

V_C and σ_C are, respectively, the volume and conductivity of the fluid removed in step (iii).

Claim 5 (original): The method of Claim 4 where V_C is at least one liter.

Claim 6 (original): The method of Claim 1 wherein the current I is alternating current having a frequency in the range from about 5 kilohertz to about 500 kilohertz.

Claim 7 (original): The method of Claim 6 wherein the current I has a frequency of about 5 kilohertz.

Claim 8 (original): The method of Claim 1 wherein the upper current-providing electrodes are placed on the subject's hands and the lower current-providing electrodes are placed on the subject's feet.

Claim 9 (original): The method of Claim 1 wherein the upper current-providing electrodes are placed on the subject's trunk and the lower current-providing electrodes are placed on the subject's thighs.

Claim 10 (original): The method of Claim 1 wherein the upper current-providing electrodes and the measuring electrodes M_{LL} and M_{RL} are carried by a common support which is placed on the subject's trunk.

Claim 11 (original): The method of Claim 1 wherein the lower current-providing electrode I_{LL} and the measuring electrode M_{LB} are carried by a first common support which is placed at least in part on the subject's left leg and the lower current-providing electrode I_{RL} and the measuring electrode M_{RB} are carried by a second common support which is placed at least in part on the subject's right leg.

Claim 12 (original): A method of controlling a peritoneal dialysis procedure comprising:

(A) continuously flowing dialysis fluid through a subject's peritoneal cavity, said flowing of dialysis fluid being capable of causing the accumulation of ultrafiltrate from the subject in the peritoneal cavity;

(B) determining the volume of fluid in the peritoneal cavity while step (A) is being performed by a bioimpedance measurement directed at the peritoneal cavity; and

(C) controlling step (A) based on the volume of fluid in the peritoneal cavity determined in step (B).

Claim 13 (original): The method of Claim 12 wherein step (B) is performed by:

(a) placing measuring electrodes M_{LL} and M_{RL} on the loins of the subject, M_{LL} being placed on the left loin and M_{RL} being placed on the right loin, M_{LL} and M_{RL} defining a loin plane;

(b) placing measuring electrodes M_{LB} and M_{RB} on the buttocks of the subject, M_{LB} being placed on the left buttock and M_{RB} being placed on the right buttock, M_{LB} and M_{RB} defining a buttock plane;

- (c) placing upper current-providing electrodes I_{LU} and I_{RU} on the subject, I_{LU} being outboard of measuring electrode M_{LL} and I_{RU} being outboard of measuring electrode M_{RL} ;
- (d) placing lower current-providing electrodes I_{RL} and I_{LL} on the subject, I_{RL} being outboard of measuring electrode M_{RB} and I_{LL} being outboard of measuring electrode M_{LB} ;
- (e) connecting upper current-providing electrode I_{LU} to upper current-providing electrode I_{RU} ;
- (f) connecting lower current-providing electrode I_{LL} to lower current-providing electrode I_{RL} ;
- (g) applying current I between the connected upper current-providing electrodes and the connected lower current-providing electrodes;
- (h) measuring the voltage Φ_L between M_{LL} and M_{LB} while current I is applied;
- (i) measuring the voltage Φ_R between M_{RL} and M_{RB} while current I is applied; and
- (j) determining the volume V of fluid in the peritoneal cavity based on the equation:

$$V = (K_p/\sigma) \bullet (L_p^2/R)$$

where:

- (1) K_p is a subject specific calibration constant;
- (2) σ is the conductivity of the fluid in the peritoneal cavity;
- (3) L_p is the distance between the loin plane and the buttock plane; and
- (4) R is the average of R_L and R_R , where

$$R_L = \Phi_L/I, \text{ and}$$

$$R_R = \Phi_R/I.$$

Claim 14 (original): The method of Claim 12 where the rate of flow of dialysis fluid into, out of, or both into and out of the peritoneal cavity is controlled in step (C).

Claim 15 (original): The method of Claim 12 where the composition of the dialysis fluid is controlled in step (C).

Claim 16 (original): The method of Claim 12 including the additional step of determining the conductivity of dialysis fluid removed from the subject while step (A) is being performed.

Claim 17 (currently amended): The method of Claim 12 wherein in step (A), the continuous flowing of dialysis fluid through the subject's peritoneal cavity is performed for a period of at least three hours and step (B) is performed at least at regular intervals throughout said period.

Claim 18 (original): The method of Claim 17 wherein step (B) is performed substantially continuously throughout said period.

Claim 19 (currently amended): The method of Claim 12 wherein in step (A), the continuous flowing of dialysis fluid through the subject's peritoneal cavity is performed for a period of at least six hours and step (B) is performed at least at regular intervals throughout said period.

Claim 20 (original): The method of Claim 19 wherein step (B) is performed substantially continuously throughout said period.

Claim 21 (original): Apparatus for determining the volume of fluid in the peritoneal cavity of a subject comprising:

- (a) measuring electrodes M_{LL} and M_{RL} for placement on the loins of the subject, M_{LL} to be placed on the left loin and M_{RL} to be placed on the right loin such that, when so placed, M_{LL} and M_{RL} define a loin plane;
- (b) measuring electrodes M_{LB} and M_{RB} for placement on the buttocks of the subject, M_{LB} to be placed on the left buttock and M_{RB} to be placed on the right buttock such that, when so placed, M_{LB} and M_{RB} define a buttock plane;
- (c) upper current-providing electrodes I_{LU} and I_{RU} for placement on the subject;
- (d) lower current-providing electrodes I_{RL} and I_{LL} for placement on the subject;
- (e) means for connecting upper current-providing electrode I_{LU} to upper current-providing electrode I_{RU} ;
- (f) means for connecting lower current-providing electrode I_{LL} to lower current-providing electrode I_{RL} ;
- (g) means for applying a current I between the connected upper current-providing electrodes and the connected lower current-providing electrodes;
- (h) means for measuring the voltage Φ_L between M_{LL} and M_{LB} while current I is applied;
- (i) means for measuring the voltage Φ_R between M_{RL} and M_{RB} while current I is applied; and
- (j) means for determining the volume V of fluid in the peritoneal cavity based on the equation:

$$V = (K_p/\sigma) \bullet (L_p^2/R)$$

where:

- (1) K_p is a subject-specific calibration constant;
- (2) σ is the conductivity of the fluid in the peritoneal cavity;
- (3) L_p is the distance between the loin plane and the buttock plane; and

(4) R is the average of R_L and R_R , where

$$R_L = \Phi_L/I, \text{ and}$$

$$R_R = \Phi_R/I.$$

Claim 22 (original): The apparatus of Claim 21 further comprising means for determining K_P , said means comprising:

- (i) means for determining the voltage Φ_{LB} between M_{LL} and M_{LB} and the voltage Φ_{RB} between M_{RL} and M_{RB} while current I is applied, said determination being made before the introduction of a predetermined volume V_C of dialysis fluid into the subject's peritoneal cavity, said dialysis fluid having a conductivity σ_C ;
- (ii) means for determining the voltage Φ_{LA} between M_{LL} and M_{LB} and the voltage Φ_{RA} between M_{RL} and M_{RB} while current I is applied, said determination being made after the introduction of a predetermined volume V_C of dialysis fluid into the subject's peritoneal cavity; and
- (iii) means for determining K_P from the equation:

$$K_P = (\sigma_C) \bullet (V_C/L_P^2) \bullet (R_B R_A) / (R_B - R_A)$$

where

$$R_B = (\Phi_{LB} + \Phi_{RB}) / (2I), \text{ and}$$

$$R_A = (\Phi_{LA} + \Phi_{RA}) / (2I).$$

Claim 23 (original): The apparatus of Claim 21 further comprising means for determining K_P , said means comprising:

- (i) means for introducing dialysis fluid into the subject's peritoneal cavity;
- (ii) means for determining the voltage Φ_{LB} between M_{LL} and M_{LB} and the voltage Φ_{RB} between M_{RL} and M_{RB} while current I is applied, said determination being made before removal of fluid from the subject's peritoneal cavity;
- (iii) means for removing fluid from the subject's peritoneal cavity;

(iv) means for measuring the volume V_C of fluid removed from the subject's peritoneal cavity;

(v) means for determining the voltage Φ_{LA} between M_{LL} and M_{LB} and the voltage Φ_{RA} between M_{RL} and M_{RB} while current I is applied, said determination being made after the removal of the volume V_C of fluid from the subject's peritoneal cavity; and

(vi) means for determining K_P from the equation:

$$K_P = (\sigma_C) \bullet (V_C / L_P^2) \bullet (R_B R_A) / (R_A - R_B)$$

where

$$R_B = (\Phi_{LB} + \Phi_{RB}) / (2I),$$

$$R_A = (\Phi_{LA} + \Phi_{RA}) / (2I), \text{ and}$$

σ_C is the conductivity of the fluid removed from the subject's peritoneal cavity.

Claim 24 (original): The apparatus of Claim 21 wherein the current I is alternating current having a frequency in the range from about 5 kilohertz to about 500 kilohertz.

Claim 25 (original): The apparatus of Claim 24 wherein the current I has a frequency of about 5 kilohertz.

Claim 26 (original): The apparatus of Claim 21 further comprising a support for carrying the upper current-providing electrodes and the measuring electrodes M_{LL} and M_{RL} .

Claim 27 (original): The apparatus of Claim 21 further comprising a first support for carrying the lower current-providing electrode I_{LL} and the measuring electrode M_{LB} and a second support for carrying the lower current-providing electrode I_{RL} and the measuring electrode M_{RB} .

Claim 28 (original): Apparatus for performing a peritoneal dialysis procedure comprising:

- (A) first means for continuously flowing dialysis fluid through a subject's peritoneal cavity, said flowing of dialysis fluid being capable of causing the accumulation of ultrafiltrate from the subject in the peritoneal cavity;
- (B) second means for determining the volume of fluid in the peritoneal cavity while dialysis fluid is flowed through the subject's peritoneal cavity, said second means comprising means for performing a bioimpedance measurement directed at the peritoneal cavity; and
- (C) third means for controlling the first means based on the volume of fluid in the peritoneal cavity determined by the second means.

Claim 29 (original): The apparatus of Claim 28 wherein the means for performing a bioimpedance measurement directed at the peritoneal cavity comprises:

- (a) measuring electrodes M_{LL} and M_{RL} for placement on the loins of the subject, M_{LL} to be placed on the left loin and M_{RL} to be placed on the right loin such that, when so placed, M_{LL} and M_{RL} define a loin plane;
- (b) measuring electrodes M_{LB} and M_{RB} for placement on the buttocks of the subject, M_{LB} to be placed on the left buttock and M_{RB} to be placed on the right buttock such that, when so placed, M_{LB} and M_{RB} define a buttock plane;
- (c) upper current-providing electrodes I_{LU} and I_{RU} for placement on the subject;
- (d) lower current-providing electrodes I_{RL} and I_{LL} for placement on the subject;
- (e) means for connecting upper current-providing electrode I_{LU} to upper current-providing electrode I_{RU} ;
- (f) means for connecting lower current-providing electrode I_{LL} to lower current-providing electrode I_{RL} ;

- (g) means for applying a current I between the connected upper current-providing electrodes and the connected lower current-providing electrodes;
- (h) means for measuring the voltage Φ_L between M_{LL} and M_{LB} while current I is applied;
- (i) means for measuring the voltage Φ_R between M_{RL} and M_{RB} while current I is applied; and
- (j) means for determining the volume V of fluid in the peritoneal cavity based on the equation:

$$V = (K_P/\sigma) \bullet (L_P^2/R)$$

where:

- (1) K_P is a subject-specific calibration constant;
- (2) σ is the conductivity of the fluid in the peritoneal cavity;
- (3) L_P is the distance between the loin plane and the buttock plane; and
- (4) R is the average of R_L and R_R , where

$$R_L = \Phi_L/I, \text{ and}$$

$$R_R = \Phi_R/I.$$

Claim 30 (original): The apparatus of Claim 28 wherein the third means controls the ultrafiltration rate of the first means.

Claim 31 (original): The apparatus of Claim 28 wherein the third means controls the rate at which the first means flows dialysis fluid through the subject's peritoneal cavity.

Claim 32 (original): The apparatus of Claim 28 wherein the third means controls the composition of the dialysis fluid which the first means flows through the subject's peritoneal cavity.

Claim 33 (original): The apparatus of Claim 28 wherein the third means includes means for determining the conductivity of the dialysis fluid removed from the subject by the first means.

Claim 34 (original): An article of manufacture comprising a computer usable medium having computer readable code means embodied therein for performing step (j) of Claim 1.

Claim 35 (original): An article of manufacture comprising a computer usable medium having computer readable code means embodied therein for performing step (iii) of Claim 2.

Claim 36 (original): An article of manufacture comprising a computer usable medium having computer readable code means embodied therein for performing step (v) of Claim 4.

Claim 37 (currently amended): Apparatus for determining the volume of fluid in the peritoneal cavity of a subject comprising a ~~programmed~~ computer which has been programmed to perform for performing step (j) of Claim 1.

Claim 38 (currently amended): Apparatus for determining the volume of fluid in the peritoneal cavity of a subject comprising a ~~programmed~~ computer which has been programmed to perform for performing step (iii) of Claim 2.

Claim 39 (currently amended): Apparatus for determining the volume of fluid in the peritoneal cavity of a subject comprising a ~~programmed~~ computer which has been programmed to perform for performing step (v) of Claim 4.

Claim 40 (new): The method of Claim 12 wherein in step (B), the bioimpedance measurement employs measuring electrodes located in the subject's loin and buttock regions.